



Ministry of Food and Drug Safety

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Certificate of Free Sales

- No. of Certificate : 20200116576
- Exporting(certifying) country : Republic of Korea
- Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following product(s) is(are) permitted to be freely sold in overseas market only.

- Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)
- Name : Asan Pharmaceutical CO., LTD.
- Address : 122-26, Giopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, Korea
- Registered No : Manufacturer IVD-4806

No. and date of product-license, comments	Classification
IVD-20-808 / SEP. 15. 2020	IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), molecular diagnostics [3]

- ※ Attached, if necessary (approved product information)
- Model(Export Name) Medical Device Accessories Manufacturer/Legal manufacturer
 - Combined/Composite medical device

Issued date : SEP. 18. 2020 (Certificate No.20200116576)

Certified by

정현철

Director
Director for Novel Products Approval
Ministry of Food and Drug Safety



Attachment

Product License No. : IVD-20-808 (SEP. 15. 2020)

Classification : IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), molecular diagnostics

Model(Export Name)

· Asan qPCR Test COVID-19

